

**THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

In re application of: SMOLA, Hans et al.

Confirmation No.: 2943

Application No.: 10/596,159

Group Art Unit: 1611

Filing Date: June 1, 2006

Examiner: PURDY, Kyle A.

For: NUTRITIONAL COMPOSITION
FOR WOUND HEALING

Attorney Docket No.: 7274-US

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPELLANT'S APPEAL BRIEF

Sir:

Appellant submits this Appeal Brief in support of the Notice of Appeal filed on May 1, 2009. This Appeal is taken from the Final Rejection in the Office Action dated March 4, 2009.

I. REAL PARTY IN INTEREST

The real party in interest for the above-identified patent application on Appeal is Nestec, S.A. by virtue of an Assignment dated September 15, 2006 and recorded at reel 018270, frame 0560 in the United States Patent and Trademark Office.

II. RELATED APPEALS AND INTERFERENCES

Appellant's legal representative and the Assignee of the above-identified patent application do not know of any prior or pending appeals, interferences or judicial proceedings which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision with respect to the above-identified Appeal.

III. STATUS OF CLAIMS

Claims 1-11 are pending in the above-identified patent application. Claims 6-11 were previously withdrawn from consideration. Claims 1-5 stand rejected. Therefore, Claims 1-5 are being appealed in this Brief. A copy of the appealed claims is included in the Claims Appendix.

IV. STATUS OF AMENDMENTS

A Non-Final Office Action was mailed on October 16, 2008, in which the Examiner rejected Claims 1-5 as obvious. Appellant filed a Response to the Non-Final Office Action on January 14, 2009, in which Appellant argued against the rejection. A Final Office Action was mailed on March 4, 2009, in which the Examiner maintained the obviousness rejection. A Notice of Appeal was filed on May 1, 2009. A copy of the Non-Final Office Action and the Final Office Action are attached as Exhibits A and B, respectively, in the Evidence Appendix.

V. SUMMARY OF CLAIMED SUBJECT MATTER

A summary of the invention by way of reference to the specification and/or figures for each of the independent claims is provided as follows:

Independent Claim 1 is directed to a nutritional composition for promoting wound healing (page 2, lines 21-22) comprising a protein source (page 2, line 22; page 4, lines 1-18), a lipid source (page 2, line 22; page 4, line 28-page 5, line 2) and a carbohydrate source (page 2, line 23; page 5, lines 4-11), the composition comprising not more than 1.8% of the total calories of the composition as arginine (page 2, lines 23-24; page 3, lines 26-32) and at least 3% of the total calories of the composition being proline (page 2, lines 24-25; page 4, lines 20-22).

Although specification citations are given in accordance with C.F.R. 1.192(c), these reference numerals and citations are merely examples of where support may be found in the specification for the terms used in this section of the Brief. There is no intention to suggest in any way that the terms of the claims are limited to the examples in the specification. As demonstrated by the references numerals and citations, the claims are fully supported by the specification as required by law. However, it is improper under the law to read limitations from the specification into the claims. Pointing out specification support for the claim terminology as is done here to comply with rule 1.192(c) does not in any way limit the scope of the claims to those examples from which they find support. Nor does this exercise provide a mechanism for circumventing the law precluding reading limitations into the claims from the specification. In short, the references numerals and specification citations are not to be construed as claim limitations or in any way used to limit the scope of the claims.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Claims 1-5 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,194,379 to McEwen et al. ("*McEwen*") in view of U.S. Patent No. 5,714,472 to Gray et al. ("*Gray*"). Copies of *McEwen* and *Gray* are attached herewith as Exhibits C and D, respectively, in the Evidence Appendix.

VII. ARGUMENT

A. LEGAL STANDARDS

Obviousness under 35 U.S.C. § 103

The Federal Circuit has held that the legal determination of an obviousness rejection under 35 U.S.C. § 103 is:

whether the claimed invention as a whole would have been obvious to a person of ordinary skill in the art at the time the invention was made...The foundational facts for the *prima facie* case of obviousness are: (1) the scope and content of the prior art; (2) the difference between the prior art and the claimed invention; and (3) the level of ordinary skill in the art...Moreover, objective indicia such as commercial success and long felt need are relevant to the determination of obviousness...Thus, each obviousness determination rests on its own facts.

In re Mayne, 41 U.S.P.Q. 2d 1451, 1453 (Fed. Cir. 1997).

In making this determination, the Patent Office has the initial burden of proving a *prima facie* case of obviousness. *In re Rijckaert*, 9 F.3d 1531, 1532, 28 U.S.P.Q. 2d 1955, 1956 (Fed. Cir. 1993). This burden may only be overcome “by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings.” *In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q. 2d 1596, 1598 (Fed. Cir. 1988). “If the examination at the initial stage does not produce a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of the patent.” *In re Oetiker*, 24 U.S.P.Q. 2d 1443, 1444 (Fed. Cir. 1992).

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the reference or references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. *In re Fine*, 837 F.2d 1071, 5, U.S.P.Q.2d 1596 (Fed. Cir. 1988). Second, there must be a reasonable expectation of success. *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 U.S.P.Q. 375 (Fed. Cir. 1986). Finally, all of the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q., 580 (CCPA 1974).

Further, the Federal Circuit has held that it is “impermissible to use the claimed invention as an instruction manual or ‘template’ to piece together the teachings of the prior art so that the

claimed invention is rendered obvious.” *In re Fritch*, 23 U.S.P.Q.2d 1780, 1784 (Fed. Cir. 1992). “One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.” *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988).

Moreover, the Federal Circuit has held that “obvious to try” is not the proper standard under 35 U.S.C. §103. *Ex parte Goldgaber*, 41 U.S.P.Q.2d 1172, 1177 (Fed. Cir. 1996). “An-obvious-to-try situation exists when a general disclosure may pique the scientist curiosity, such that further investigation might be done as a result of the disclosure, but the disclosure itself does not contain a sufficient teaching of how to obtain the desired result, or that the claimed result would be obtained if certain directions were pursued.” *In re Eli Lilly and Co.*, 14 U.S.P.Q.2d 1741, 1743 (Fed. Cir. 1990).

Of course, references must be considered as a whole and those portions teaching against or away from the claimed invention must be considered. *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve Inc.*, 796 F.2d 443 (Fed. Cir. 1986). “A prior art reference may be considered to teach away when a person of ordinary skill, upon reading the reference would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the Applicant.” *Monarch Knitting Machinery Corp. v. Fukuhara Industrial Trading Co., Ltd.*, 139 F.3d 1009 (Fed. Cir. 1998), quoting, *In re Gurley*, 27 F.3d 551 (Fed. Cir. 1994).

B. THE CLAIMED INVENTION

Independent Claim 1 is directed to a nutritional composition for promoting wound healing. The composition includes a protein source, a lipid source and a carbohydrate source. The composition includes no more than 1.8% of the total calories of the composition as arginine. At least 3% of the total calories of the composition is proline.

C. THE REJECTION OF CLAIMS 1-5 UNDER 35 U.S.C. §103(a) SHOULD BE REVERSED BECAUSE THE EXAMINER HAS FAILED TO ESTABLISH A *PRIMA FACIE* CASE OF OBVIOUSNESS

Appellant respectfully submits that the obviousness rejection of Claims 1-5 should be reversed because the Examiner has failed to establish a *prima facie* case of obviousness. In the Final Office Action, the Examiner alleged that the combination of *McEwen* in view of *Gray* renders the claimed subject matter obvious. See, Final Office Action, pages 2-5. However, the Examiner has failed to establish a *prima facie* case of obviousness because there exists no reason why the skilled artisan would have combined *McEwen* and *Gray* to arrive at the presently claimed subject matter.

Independent Claim 1 recites, in part, a nutritional composition for promoting wound healing comprising not more than 1.8% of the total calories of the composition as arginine and at least 3% of the total calories of the composition being proline. In recent years, much attention has focused on the role of arginine in wound healing. An adequate supply of arginine is clearly relevant to the wound healing process. However, arginine is also a precursor for the formulation of nitric oxide which acts as a vasodilator and enhances growth hormone secretion. It is not desirable for critically ill individuals to be exposed to high amounts of nitric oxide and yet this will inevitably happen if such individuals receive nutritional supplements containing high levels of arginine.

Further, it is quite likely that a high proportion of elderly, bedridden or critically ill patients at risk of developing pressure sores will also suffer from conditions for which high levels of nitric oxide are contra-indicated. See, specification, page 2, lines 8-17. Accordingly, the present invention is supplemented with proline in a quantity sufficient to facilitate collagen synthesis and small amounts of arginine that account for no more than 1.8% of the total calories of the compositions. See, specification, page 3, lines 9-32. In contrast, Appellant respectfully submits that the skilled artisan would have no reason to combine the cited references to arrive at the present claims because *Gray* teaches away from *McEwen* and from the present claims.

1. *Gray* teaches away from *McEwen*

Appellant respectfully submits that *Gray* teaches away from combination with *McEwen* with respect to the amount of arginine required in the composition. For example, *Gray* explicitly discloses "at least 3% of the total calories as arginine." *Gray* further discloses that "[e]nhanced wound healing with arginine is believed to be provided at quantities greater than 3% of the total calories." See, *Gray*, col. 6, lines 58-62 (emphasis added). Accordingly, *Gray* explicitly teaches that, at the very least, 3% of the total calories of the composition are from arginine. This is in direct contrast to *McEwen*, which discloses compositions comprising about 1% arginine with respect to the total calories of the nutritional products. Specifically, *McEwen* discloses that "[d]esirably, the arginine will comprise about 1% of the total calories of the nutritional products." See, *McEwen*, col. 9, lines 3-5. Indeed, *McEwen* explicitly teaches that an amount of arginine may be used in a composition that is much lower in the arginine content required by *Gray*.

Further, *Gray* also teaches away from combination with *McEwen* with respect to the amount of proline required in the composition. For example, the Examiner admits that column 6 of *Gray* discloses proline in an amount of about 1.5% and asserts that *Gray* also teaches a composition containing "at least 2.0%" proline. See, Final Office Action, page 2, lines 19-22. As such, the Examiner cites *Gray*, at least in part, for the disclosure of a minimum amount of proline in the disclosed compositions. This is in direct contrast to *McEwen*, which fails to disclose or even suggest the use of proline. Instead, *McEwen* is entirely directed toward an elemental liquid nutritional product useful for providing nutrition to a patient having a malabsorption condition by enterally feeding to the patient a nutritional composition having a specific caloric density. See, *McEwen*, Abstract. *McEwen* fails to even disclose the use of proline in a nutritional composition at any place in the disclosure, let alone a minimum amount of proline, including, for example, at least 2% of the total calories of the composition being proline.

As such, because the cited references disclose completely different amounts of arginine and proline, the skilled artisan would have no reason to combine *Gray* with *McEwen* to arrive at the present claims. In fact, what the Examiner has done here is to apply hindsight reasoning by attempting to selectively piece together teachings of each of the references in an attempt to recreate what the claimed invention discloses. Instead, the skilled artisan must have a reason to

combine the cited references to arrive at the present claims. Appellant respectfully submits that such a reason is not present in the instant case.

Appellant also respectfully submits that each reference must be considered as a whole and those portions teaching against or away from each other and/or the claimed invention must be considered. *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve Inc.*, 796 F.2d 443 (Fed. Cir. 1986). “A prior art reference may be considered to teach away when a person of ordinary skill, upon reading the reference would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the Applicant.” *Monarch Knitting Machinery Corp. v. Fukuhara Industrial Trading Co., Ltd.*, 139 F.3d 1009 (Fed. Cir. 1998), quoting, *In re Gurley*, 27 F.3d 551 (Fed. Cir. 1994).

2. Gray teaches away from the present claims

Appellant also respectfully submits that *Gray* teaches away from the presently claimed subject matter. Specifically, in its attempt to arrive at the present claims by combining the cited references, the Examiner has ignored significant portions of *Gray* that teach away from the presently claimed subject matter. For example, the formulations of *Gray* are explicitly disclosed as including “at least 3% of the total calories as arginine.” *Gray* further discloses that “[e]nhanced wound healing with arginine is believed to be provided at quantities greater than 3% of the total calories.” See, *Gray*, col. 6, lines 58-62 (emphasis added). As discussed above, this is in direct contrast to the present claims, which require, in part, a nutritional composition for promoting wound healing comprising not more than 1.8% of the total calories of the composition as arginine.

As is discussed above, arginine is a precursor for the formulation of nitric oxide which acts as a vasodilator and enhances growth hormone secretion. It is not desirable for critically ill individuals to be exposed to high amounts of nitric oxide and yet this will inevitably happen if such individuals receive nutritional supplements containing high levels of arginine. It is also quite likely that a high proportion of elderly, bedridden or critically ill patients at risk of developing pressure sores will also suffer from conditions for which high levels of nitric oxide are contra-indicated. See, specification, page 2, lines 8-17. Accordingly, the present invention is supplemented with small amounts of arginine that account for not more than 1.8% of the total

calories of the compositions. See, specification, page 3, lines 9-32. *Gray* specifically teaches away from the claimed subject matter when *Gray* teaches that the composition contains “at least 3% of the total calories as arginine.” See, *Gray*, col. 6, lines 58-62 (emphasis added).

Thus, Appellant respectfully submits that this disclosure of *Gray* would actually lead the skilled artisan in a direction divergent from the path that was taken by Appellant in the present disclosure. *In re Haruna*, 249 F.3d 1327 (Fed. Cir. 2001). See, also, MPEP 1504.03. In other words, the explicit teaching of *Gray* that the composition contains “at least 3% of the total calories as arginine” would direct the skilled artisan to include more arginine than is required or taught by the present claims, which include arginine in amounts that are not more than 1.8% of the total calories of the compositions. As a result, one having ordinary skill in the art would have no reason to combine the cited references to arrive at the present claims. For the reasons discussed above, Appellant respectfully submits that Claims 1-5 are novel, nonobvious and distinguishable from the cited reference.

Accordingly, Appellant respectfully requests that the rejection of Claims 1-5 under 35 U.S.C. §103(a) be withdrawn.

VIII. CONCLUSION

Appellant respectfully submits that the Examiner has failed to establish a *prima facie* case of obviousness under 35 U.S.C. §103 with respect to the rejection of Claims 1-5. Accordingly, Appellant respectfully submits that the obviousness rejections are erroneous in law and in fact and should therefore be reversed by this Board.

The Director is hereby authorized to charge the fee of \$540.00 to Deposit Account No. 50-4498 in the name of Nestle Nutrition to cover the cost of the Appeal Brief. The Director is authorized to charge any additional fees that may be required, or to credit any overpayment to Deposit Account No. 50-4498.

Respectfully submitted,

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CLAIMS APPENDIX

**PENDING CLAIMS ON APPEAL OF
U.S. PATENT APPLICATION SERIAL NO. 10/596,159**

1. A nutritional composition for promoting wound healing comprising a protein source, a lipid source and a carbohydrate source, the composition comprising not more than 1.8% of the total calories of the composition as arginine and at least 3% of the total calories of the composition being proline.
2. A nutritional composition according to Claim 1 wherein at least 3.5% of the total calories of the composition are proline.
3. A nutritional composition according to claim 1 wherein 1.5% of the total calories of the composition are arginine.
4. A nutritional composition according to claim 1 wherein the protein source comprises at least 28% of the total calories of the composition.
5. A nutritional composition according to claim 1 wherein the composition has an energy density of about 1.25 kcal/ml.

EVIDENCE APPENDIX

EXHIBIT A: Non-Final Office Action mailed October 16, 2008

EXHIBIT B: Final Office Action mailed March 4, 2009

EXHIBIT C: U.S. Patent No. 6,194,379 to McEwen et al. ("*McEwen*")

EXHIBIT D: U.S. Patent No. 5,714,472 to Gray et al. ("*Gray*")

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RELATED PROCEEDINGS APPENDIX

None.